



UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION

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IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION

MDL NO. 2804

Track One

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PRELIMINARY EXPERT REPORT AND DISCLOSURE OF  
SONYA KWON  
ANKURA CONSULTING

MAY 10, 2019

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER



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## **I. PROFESSIONAL BACKGROUND AND EXPERIENCE**

1. I am a Senior Managing Director at Ankura Consulting Group ("Ankura"), a provider of litigation and disputes consulting services with over 1,400 professionals worldwide. I lead the Complex Data and Statistical Analysis practice and specialize in the application of financial, statistical, and complex data-intensive analyses to legal and regulatory issues. My education includes a B.A. in Economics from the University of California, Berkeley and an M.B.A. from the University of California, Los Angeles. In addition to Ankura, I have worked at Navigant Consulting, Inc., Deloitte & Touche LLP, PricewaterhouseCoopers LLP, and Arthur Andersen LLP. At all of these firms, I developed and implemented national complex data analysis programs and courses.
2. My qualifications are summarized in greater detail in my curriculum vitae, which is attached as Appendix A. Over the past twenty years, I have been involved in a number of complex litigation matters involving a range of issues, including data collection, conversion, management and statistical, economic or data-intensive analysis. I have worked on numerous litigation matters, requiring the collection and analysis of large volumes of data (including shipment, distribution, and retail data). I also have experience in preparing or providing expert testimony for financial, economic, statistical and data-intensive related analyses.

## **II. GENERAL BACKGROUND AND SCOPE OF ASSIGNMENT**

3. This matter relates to claims made by the County of Cuyahoga and County of Summit, Ohio against various manufacturers and distributors, including CVS Indiana, L.L.C. and CVS Rx Services, Inc. ("CVS").<sup>1</sup> These CVS entities operate two distribution centers which ship prescription drugs to CVS retail pharmacies ("CVS pharmacies") so that the pharmacies have inventory to fill prescriptions for patients. These CVS distribution entities are identified in the Complaints as Distributor Defendants.<sup>2</sup>
4. Plaintiffs allege that "various entities in the supply chain failed to design and operate systems to identify suspicious orders of prescription opioids, maintain effective controls against diversion, and halt suspicious orders when they were identified, thereby contributing to the oversupply of such

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<sup>1</sup> Second Amended Corrected Complaint, *County of Cuyahoga v. Purdue Pharma L.P.*, No. 17-OP-45004 (May 30, 2018), ECF No. 522; Third Amended Complaint, *County of Summit v. Purdue Pharma L.P.*, No. 18-OP-45090 (Apr. 25, 2018 N.D. Ohio), ECF No. 1466 (together "Summit and Cuyahoga Complaints.")

<sup>2</sup> Plaintiffs initially sued CVS Health Corporation, but the Court granted Plaintiffs' unopposed motion to dismiss CVS Health from the Track One cases without prejudice and to add CVS Indiana, LLC and CVS Rx Services, Inc. as Defendants. *Unopposed Motion to Dismiss Party CVS Health Corporation and add CVS Indiana, LLC and CVS RX Services, Inc.*, In re: National Prescription Opiate Litigation, 17-md-2804 (June 19, 2019 N.D. Ohio), ECF No. 637 & June 20, 2018 text order granting motion.



drugs and fueling an illegal secondary market.”<sup>3</sup>

5. Plaintiffs further allege that actions by Distributor Defendants, including CVS, are a “substantial cause for the volume of prescription opioids plaguing Plaintiff’s community.”<sup>4</sup>
6. I have been retained by Zuckerman Spaeder LLP (“Counsel”), on behalf of CVS, to review the data relevant to the claims in this matter and to prepare certain analyses to assist the trier of fact in evaluating the distribution of certain prescription opioids into Cuyahoga and Summit Counties by CVS distribution centers.
7. The hourly rate currently charged by Ankura for my services in connection with this matter is \$750/hour and the hourly rates for other Ankura professionals assisting me range from \$280/hour to \$600/hour. Ankura’s compensation does not depend on either the findings of my review or the outcome of this case.
8. I have prepared this report based on the work my team and I have performed to date and the information available to me as of the date of this report. I understand that I may be asked to testify regarding my opinions contained herein. Due to the ongoing nature of this litigation, I reserve the right to change, amend, modify or supplement my opinions based on any additional information that I may be asked to consider or any additional analyses that I may be asked to perform.

### **III. INFORMATION RELIED UPON**

9. In preparing this report, I reviewed the following data produced in this matter.
  - a. CVS Distribution Data: Shipment information of controlled and non-controlled items from CVS to CVS pharmacies in Cuyahoga and Summit Counties<sup>5</sup> for 07/29/2002 to 08/25/2018 from CVS’s mainframe system. The distribution data consists of pharmacy items including controlled and non-controlled drugs and does not include over-the-counter medication shipped to CVS stores for sale from the front of the store (i.e., not from the store pharmacy).<sup>6</sup> This information includes the CVS store number to which the order was shipped,<sup>7</sup> the date on which financial responsibility for the order transferred from CVS to the

<sup>3</sup> Summit and Cuyahoga Complaints, paragraph 9.

<sup>4</sup> Summit and Cuyahoga Complaints, paragraph 81.

<sup>5</sup> CVS Indiana, L.L.C.’s and CVS RX Services, Inc.’s Amended Objections and Responses to Interrogatories No. 1-6, 8-10, 13, 15-18, 20-21 and 30 of Plaintiffs’ First Set of Interrogatories, September 10, 2018, p.5.

<sup>6</sup> John Andrade, Senior Manager, Application Development, IS – Retail Systems – Logistics

<sup>7</sup> Customer Number contains the seven-digit number that is used to identify CVS stores that received the shipment. If the first two numbers in Customer Number field are zeros, then the CVS Store number is the last five digits of that number. When the first two numbers are “04,” then the CVS Store number begins at the third digit and ends at the sixth digit.



pharmacy ("Bill\_Date\_R"), the number of packages shipped ("Regular Quantity"), the number of dosage units shipped within each package ("Size"), and the National Drug Code ("NDC number") and drug name included in the shipment.<sup>8</sup> The NDC number and drug name for all items other than the prescription opioids at issue in this matter are redacted. The data also includes a "Drug Control Indicator" that is set to "1" if the transaction relates to a drug that was controlled in any state<sup>9</sup> or that the DEA has scheduled<sup>10</sup> in Class II through V as of the date the transaction occurred. The data in this listing is limited to shipments into Cuyahoga and Summit Counties.

- b. Cardinal Health Distribution Data: Shipment information related to controlled and non-controlled medication from Cardinal Heath to CVS pharmacies and non-CVS stores and pharmacies from 01/01/1996 to 05/29/2018. The data in this listing is not limited to shipments into Cuyahoga and Summit Counties.
- c. Automation of Reports and Consolidated Orders System ("ARCOS") Data: ARCOS is the reporting system developed by the Drug Enforcement Agency ("DEA") designed to supervise the movement of controlled substances from manufacturers, through distribution channels, to dispensers and retailers.<sup>11</sup> The ARCOS data produced in this matter includes nationwide shipments of controlled medication between distributors, manufacturers, dispensers, labs, and shipments for destruction, including shipments by CVS distribution centers, shipments to CVS pharmacies, and shipments involving entities unrelated to CVS from 01/01/2006 to 12/31/2014. The ARCOS data that has been produced includes information on 14 opioids,<sup>12</sup> and *may* contain data on prescription opioids outside of the scope of the discovery orders in this matter. It is not limited to shipments into Cuyahoga and Summit Counties. Shipments to these counties can be identified using both the "Buyer State" and "Buyer County" fields. The data also includes the name, registered DEA number, and business type for the reporter and buyer on the transaction,<sup>13</sup> the Drug Code, NDC Number, and Drug Name involved in the shipment, the type of transaction ("Transaction Code"),<sup>14</sup> the number of packages shipped ("Quantity"), the strength of the drug shipped,<sup>15</sup> the total number of doses shipped ("Dosage

<sup>8</sup> See footnote 6.

<sup>9</sup> The item may not have been controlled by the DEA or in Ohio at the time of the transaction, but rather in another state. Jason Crocker, Rx Item Manager.

<sup>10</sup> DEA Drug Scheduling Actions: <https://www.deadiversion.usdoj.gov/schedules/>.

<sup>11</sup> "Background: What is ARCOS and what does it do?": <https://www.deadiversion.usdoj.gov/arcos/index.html>.

<sup>12</sup> Buprenorphine, Codeine, Dihydrocodeine, Fentanyl, Hydrocodone, Hydromorphone, Levorphanol, Meperidine, Methadone, Morphine, Opium (Powdered), Oxycodone, Oxymorphone, and Tapentadol.

<sup>13</sup> This information is included in the following fields: Reporter\_DEA\_Number, Reporter\_Name, Reporter\_Bus\_Act, Buyer\_DEA\_Number, Buyer\_Name, and Buyer\_Bus\_Act.

<sup>14</sup> The three most common values are "S" (sale, disposition, or transfer), "P" (purchase or receipt), and "Y" (destroyed).

<sup>15</sup> The strength denotes the purity of the shipped drug for raw powders as well as partial box shipments.



Unit"), the total weight of the base form of the drug ("Calc Base Weight in Grams"), and the date of the shipment ("Transaction Date").

- d. National Drug Code ("NDC Dictionary"):<sup>16</sup> Listing of medications controlled by the DEA. The data identifies drugs by NDC number ("NDC") and name ("Trade/Product Name"). The NDC Dictionary also includes information about the form of the drug (e.g., tablet, lozenge or syrup ("Package Measure")), the number of dosage units contained in each package ("Package Quantity") and the number, name and weight of active ingredients contained in the drug ("No. Ingredients", "Ingredient Name", "Ingredient Base Weight"), and DEA drug scheduling information ("CSA Schedule"). For my analysis, I used the NDC Dictionary published on April 3<sup>rd</sup>, 2019.<sup>17</sup>
10. I have also considered documents and depositions produced to date in this matter by the parties, as well as publicly available information. A complete list of materials I have considered is included as Appendix B to this report.
11. In addition, I had conversations with the following CVS personnel.
  - a. John Andrade, Senior Manager, Application Development, IS - Retail Systems- Logistics
  - b. Jason Crocker, Rx Item Manager
  - c. Brian Whalen, Vice President, Pharmacy Merchandising

#### **IV. DATA PREPARATION**

12. The ARCOS Data is compiled by the DEA and contains transaction details for fourteen distinct opioids from one entity to another.<sup>18</sup> The data contains transactions across sixty states and territories. These transaction records contain information detailing seller information, buyer information, NDC and quantity information, as well as a sequential order number and dates the transaction was shipped. For the purposes of my analyses, I both excluded records and supplemented ARCOS with reliable data to create a complete data set. A complete description of this data preparation process is included as Appendix C to this report.
13. My final ARCOS analysis data set contains 2,449,786 records.

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<sup>16</sup> "National Drug Code Dictionary", <https://www.deadiversion.usdoj.gov/arcos/ndc/ndcfile.txt>.

<sup>17</sup> "NDC Dictionary Instructions", <https://www.deadiversion.usdoj.gov/arcos/ndc/readme.txt>.

<sup>18</sup> The ARCOS data produced in this matter contains 500,709,803 records.



## **V. DATA VALIDATION**

14. I compared the shipments of HCPs between the CVS distribution data and ARCOS data. First, I used the "Bill Date R" field to filter the CVS distribution data to transactions shipped between 01/01/2006 through 12/31/2014, the period captured in the ARCOS data. Next, I further filtered the CVS distribution data to HCP shipments into Cuyahoga and Summit Counties by filtering to transactions in which the NDC number is not redacted and used the NDC number to match each of the remaining transactions with the anhydrous base weight of the active ingredient from the DEA NDC Dictionary.<sup>19</sup> Then, I summarized the filtered data by NDC number to calculate the total weight and number of shipments.
15. I filtered the ARCOS data<sup>20</sup> to reflect only shipments into Cuyahoga and Summit Counties using the "Buyer County" field and excluded shipments from non-CVS distributors using the "Reporter Name" field. I also filtered the data to hydrocodone shipments where the "Drug Code" had a value of "9193." Finally, I summarized the remaining transactions by NDC number to find the total weight and number of shipments.
16. I compared the summaries of HCP transactions and total weight from the ARCOS and CVS distribution data described in the preceding paragraphs. I determined both datasets capture the same shipments with similar number of packages and active ingredient weights. My comparison is included as Exhibit 1.

## **VI. SUMMARY OF OPINIONS**

17. Based on my professional experience, the data and information reviewed, and the analysis performed, I conclude the following:
- a. The CVS distribution data and ARCOS data show that CVS distribution centers did not ship to non-CVS stores in Cuyahoga County and Summit County during the period analyzed.
  - b. The ARCOS data and CVS distribution data corroborate that CVS did not distribute Schedule II drugs into Cuyahoga and Summit counties during the period analyzed.
  - c. The CVS distribution data and ARCOS data show that CVS distribution centers only shipped hydrocodone combination products ("HCPs") when they were classified as Schedule III controlled substances and did not ship HCPs into Cuyahoga and Summit counties after the DEA rescheduled them to Schedule II.

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<sup>19</sup> NDC Dictionary, <https://www.deadiversion.usdoj.gov/arcos/ndc/ndcfile.txt>.

<sup>20</sup> This analysis uses the filtered ARCOS data, as described in Section III of this report.



- d. The ARCOS data shows that CVS distributed less than 2.5% of relevant opioids into Cuyahoga and Summit counties between 2006 and 2014 and distributed an estimated 1.6% of total relevant opioids into Cuyahoga and Summit counties between 2006 and 2018.
- e. Between 2006 and 2013, CVS shipments of HCPs increased at a slower rate than the annual DEA quota for hydrocodone.
- f. Between 2006 and 2014, non-controlled substances represent approximately 90% of dosage units shipped to CVS pharmacies in Cuyahoga and Summit counties by CVS distribution centers.
- g. Between 2006 and 2014, HCPs represented less than 2.5% of total dosage units shipped to CVS pharmacies in Cuyahoga and Summit counties by CVS distribution centers.
- h. Between 2006 and 2014, controlled substances represent less than 13.5% of total dosage units shipped to CVS pharmacies in Cuyahoga and Summit counties by CVS and Cardinal Health.
- i. Between 2006 and 2014, HCPs represent less than 3.1% of total dosage units shipped to CVS pharmacies in Cuyahoga and Summit counties by CVS and Cardinal Health.
- j. Between 2006 and 2014, CVS pharmacies in Cuyahoga and Summit counties ordered a small percentage of HCPs from Cardinal Health.

## **VII. CVS DISTRIBUTED ONLY TO CVS PHARMACIES**

18. The CVS distribution centers at issue in this case distributed prescription drugs only to CVS pharmacies. CVS's corporate representative testified that these CVS distribution centers "have only distributed controlled substances to CVS pharmacies."<sup>21</sup> CVS discovery responses likewise indicate that CVS's distribution centers "did not distribute hydrocodone combination products [the only relevant prescription opioid shipped by CVS] to any pharmacies in Cuyahoga and Summit Counties other than the CVS CT1 pharmacies."<sup>22</sup>
19. To confirm this testimony, I analyzed the CVS distribution data to evaluate the recipients of shipments from CVS in Cuyahoga and Summit Counties. I reviewed the store numbers receiving shipments from CVS Distributors and found that all shipments from CVS were shipped to CVS pharmacies. A listing of these 85 stores is included in Exhibit 2A.<sup>23</sup> The total number of shipments to these stores is shown in Table 1, below.

<sup>21</sup> Deposition of Mark Vernazza, November 20, 2018, p. 56, line 10.

<sup>22</sup> CVS Indiana, L.L.C.'s and CVS RX Services, Inc.'s Amended Objections and Responses to Interrogatories No. 1-6, 8-10, 13, 15-18, 20-21 and 30 of Plaintiffs' First Set of Interrogatories, September 10, 2018, p. 8.

<sup>23</sup> There are 69 CVS stores in the distribution data with shipments between 1/1/2006 and 9/30/2014.





**Table 1: Total Shipments to CVS Pharmacies in Cuyahoga and Summit Counties from CVS Distribution Centers (CVS Distribution Data)**

Year	Total # of Shipments to CVS Pharmacies	# of Shipments Controlled Substances to CVS Pharmacies	Total # of Shipments by CVS Distribution Centers to Non-CVS Stores
2002	471,399	23,093	0
2003	1,074,542	54,967	0
2004	1,105,264	52,906	0
2005	1,239,570	60,822	0
2006	1,242,175	66,904	0
2007	1,241,097	68,079	0
2008	1,243,839	71,772	0
2009	1,144,654	66,413	0
2010	1,091,329	63,355	0
2011	1,055,579	60,999	0
2012	1,068,846	62,191	0
2013	1,098,039	64,009	0
2014	1,113,103	54,776	0
2015	1,114,552	45,758	0
2016	1,105,448	47,328	0
2017	1,165,695	49,814	0
2018	809,627	34,566	0
<b>Total:</b>	<b>18,384,758</b>	<b>947,752</b>	<b>0</b>

20. I also analyzed the ARCOS data, filtered as described above in Section III, to evaluate the buyers of CVS shipments into Cuyahoga and Summit Counties. I found all shipments reported in the ARCOS data by CVS distribution centers were shipped to CVS pharmacies. A listing of these 69 stores is included in Exhibit 2A.

**Table 2: Total Shipments from CVS Reporters into Cuyahoga and Summit Counties (ARCOS Data)**

Year	# of Shipments to CVS Pharmacies	# of Shipments to non-CVS Buyers
2006	15,069	0
2007	17,289	0
2008	17,896	0
2009	16,447	0
2010	16,551	0
2011	16,771	0



2012	17,142	0
2013	18,805	0
2014	11,469	0
<b>Total</b>	<b>147,439</b>	<b>0</b>

### VIII. CVS NEVER DISTRIBUTED SCHEDULE II OPIOIDS, SUCH AS OXYCODONE, INTO CUYAHOGA AND SUMMIT COUNTIES

21. The DEA categorizes “drugs, substances, and certain chemical used to make drugs” into various schedules based, in part, on the potential for abusing the drug.<sup>24</sup> The Court has limited discovery in this case to “opioid products that are or ever were classified as Schedule II under the Controlled Substances Act.”<sup>25</sup> The DEA defines Schedule II drugs as “drugs with a high potential for abuse, with use potentially leading to severe psychological or physical dependence.”<sup>26</sup> Prescription opioids such as oxycodone and fentanyl are, and always have been, Schedule II controlled substances.
22. CVS’s corporate representative testified that the CVS distribution centers at issue “are now, and have always been, only distributors of Schedule III through V controlled substances, and have never been distributors of Schedule II controlled substances.”<sup>27</sup> Thomas Moffatt, Vice President, Assistant Secretary and Assistant General Counsel of CVS Health, who has worked at CVS for over 20 years, also testified that to his knowledge, CVS has never distributed a Schedule II drug.<sup>28</sup> Additionally, Mark Nicastro, Director of the Indianapolis CVS Distribution Center, testified in his deposition that CVS distribution centers “do not carry C-II’s.”<sup>29</sup>
23. Thomas Moffatt also testified that CVS’s DEA registrations “are for Schedules III through V;”<sup>30</sup> and Ronald Link, former Senior VP of Logistics for CVS Pharmacy, and John Mortelliti, Director of Asset Protection Supply Chain for CVS Health, confirmed that Schedule II drugs shipped to CVS pharmacies were supplied from outside vendors.<sup>31</sup>
24. I confirmed this testimony by reviewing the shipments reported in the ARCOS data. As part of my analysis, I used the ARCOS data to evaluate the distributor information for prescription medication classified as Schedule II controlled substances by the DEA. ARCOS Data shows that after filtering the

<sup>24</sup> “Drugs, substances, and certain chemicals used to make drugs are classified into (5) distinct categories or schedules depending upon the drug’s acceptable medical use and the drug’s abuse or dependency potential. The abuse rate is a determinate factor in the scheduling of the drug.” <https://www.dea.gov/drug-scheduling>.

<sup>25</sup> Discovery Ruling No. 2, Doc. No. 693 (June 30, 2018), p. 3.

<sup>26</sup> <https://www.dea.gov/drug-scheduling>.

<sup>27</sup> Deposition of Mark Vernazza, November 20, 2018, p. 56, line 5.

<sup>28</sup> Deposition of Thomas Moffatt, January 15, 2019, p. 37, line 24 - p. 38, line 2.

<sup>29</sup> Deposition of Mark Nicastro, December 6, 2018, p. 37, line 5.

<sup>30</sup> Deposition of Thomas Moffatt, January 15, 2019, p. 39, line 4.

<sup>31</sup> Deposition of Ronald Link, December 11, 2018, p. 26, line 9 and p. 35, line 18; Deposition of John Mortelliti, January 23, 2019, p. 209, line 23.



transactions to shipments of Schedule II medication to Cuyahoga and Summit Counties, out of the 14 opioids<sup>32</sup> relevant to this matter there are no shipments of any Schedule II opioids by CVS distribution centers.

**IX. CVS DISTRIBUTED HYDROCODONE COMBINATION PRODUCTS ONLY WHEN THEY WERE CLASSIFIED AS SCHEDULE III AND CEASED DISTRIBUTING THEM WHEN THEY WERE RE-CLASSIFIED AS SCHEDULE II**

25. CVS shipment data and ARCOS data shows CVS shipped HCPs through September 2014. During this time, HCPs were classified as Schedule III controlled substances. According to the DEA, Schedule III drugs are "drugs with a moderate to low potential for physical and psychological dependence. Schedule III drugs abuse potential is less than Schedule I and Schedule II drugs."<sup>33</sup>
26. Effective October 6<sup>th</sup>, 2014,<sup>34</sup> the DEA rescheduled HCPs from Schedule III to Schedule II.<sup>35</sup> Because these products became Schedule II controlled substances on this date, they fall within the universe of prescription opioids subject to discovery in this case even though they were not classified as Schedule II controlled substances before then. "Hydrocodone Combination Products are the only products ever distributed by the CVS Distributors into Cuyahoga and Summit Counties that meet this definition."<sup>36</sup>
27. Notably, once the DEA rescheduled HCPs to Schedule II, CVS stopped distributing HCPs to its stores. CVS's corporate representative testified that "CVS ceased the distribution of hydrocodone combination products upon those products being upscheduled to Schedule II in October of 2014."<sup>37</sup> Additionally, CVS discovery responses reflect that "the CVS Distributors have not distributed hydrocodone combination products since they were reclassified as Schedule II on October 6, 2014."<sup>38</sup>
28. In addition to reviewing deposition testimony and discovery responses, I analyzed the CVS distribution data for shipments of HCPs to Cuyahoga and Summit Counties.<sup>39</sup> I found that CVS distribution centers did not ship HCPs after September 2014. This finding is consistent with the testimony referenced above. Chart 1, below, shows the percentage of all shipments of HCP packages

<sup>32</sup> Buprenorphine, Codeine, Dihydrocodeine, Fentanyl, Hydrocodone, Hydromorphone, Levorphanol, Meperidine, Methadone, Morphine, Opium (Powdered), Oxycodone, Oxymorphone, and Tapentadol.

<sup>33</sup> <https://www.dea.gov/drug-scheduling>.

<sup>34</sup> DEA Drug Scheduling Actions, <https://www.deadiversion.usdoj.gov/schedules/>.

<sup>35</sup> <https://www.govinfo.gov/app/details/FR-2014-08-22/2014-19922>.

<sup>36</sup> CVS Indiana, L.L.C.'s and CVS RX Services, Inc.'s Amended Objections and Responses to Interrogatories No. 1-6, 8-10, 13, 15-18, 20-21 and 30 of Plaintiffs' First Set of Interrogatories, September 10, 2018, p. 5.

<sup>37</sup> Deposition of Mark Vernazza, November 20, 2018, 2018, p. 20, line 2-5.

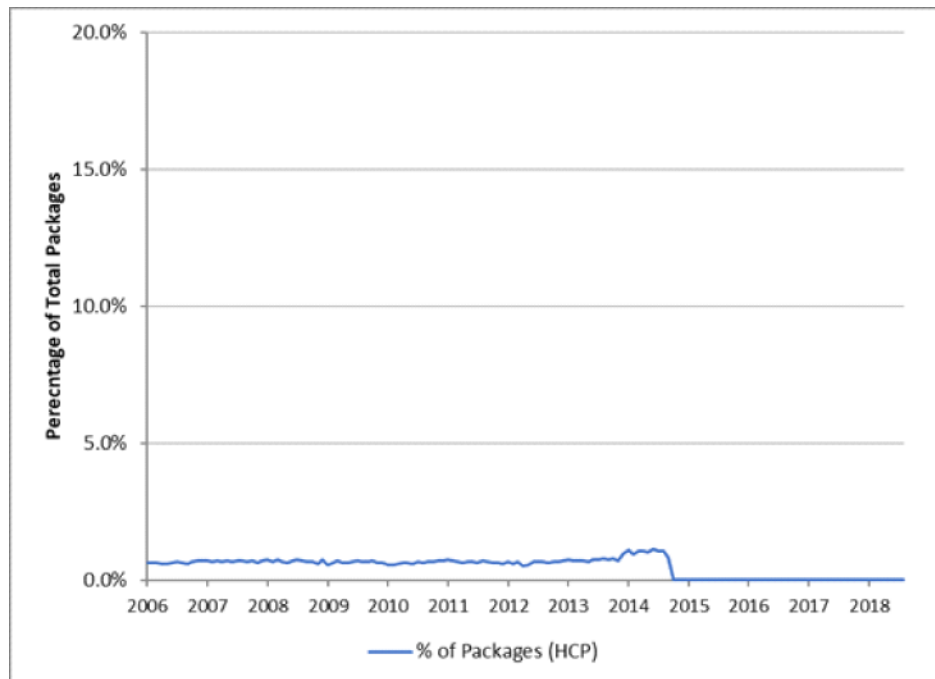
<sup>38</sup> CVS Indiana, L.L.C.'s and CVS RX Services, Inc.'s Amended Objections and Responses to Interrogatories No. 1-6, 8-10, 13, 15-18, 20-21 and 30 of Plaintiffs' First Set of Interrogatories, September 10, 2018, p. 5.

<sup>39</sup> The NDC number and drug name are redacted in the CVS Shipment Data for all drugs other than the prescription opioids at issue in this case, which for CVS is only HCPs.



from CVS distribution centers to pharmacies in Cuyahoga and Summit counties by year. As noted above, the only pharmacies to which CVS distribution centers shipped HCPs were CVS pharmacies.

**Chart 1: CVS Distribution Center Shipments of HCPs to CVS Pharmacies in Cuyahoga and Summit Counties (CVS Distribution Data)**



29. I also evaluated CVS shipments reported in the ARCOS data<sup>40</sup> and found shipments of HCPs from CVS through September 2014, but no shipments after the DEA rescheduled HCPs to Schedule II in October 2014. Specifically, the ARCOS data reflects that CVS Indiana, L.L.C. last shipped an HCP on April 9, 2014 and CVS Rx Services, Inc. last shipped an HCP on September 24, 2014 into Cuyahoga and Summit counties.<sup>41</sup>

#### **X. CVS DISTRIBUTED 1.6% OF PRESCRIPTION OPIOIDS INTO CUYAHOGA AND SUMMIT COUNTIES**

30. To determine CVS's share of prescription opioid distributions in Cuyahoga and Summit Counties, I compared the volume of prescription opioids distributed by CVS to the volume of prescription opioids shipped by all distributors. I focused my analysis to Discovery Ruling No. 2, which limited discovery to "opioid products that are or ever were classified as Schedule II under the Controlled Substances Act,"

<sup>40</sup> This analysis uses the filtered ARCOS data, as described in Section IV of this report.

<sup>41</sup> This is consistent with the last date in the CVS distribution data of September 24, 2014.



including "branded, unbranded, and generic drugs."<sup>42</sup> As explained above, the only products CVS distributed within this definition were HCPs.

31. In order to quantify the appropriate amount of opioids being distributed, I used the Morphine Milligram Equivalence (MME) calculation. MME is a guideline on "dosage of opioids for treatment of chronic pain" set by the CDC.<sup>43</sup> MME allows dosage amounts within one family of opioid products (i.e. oral hydrocodone combination products) to be compared against each other.<sup>44</sup> I used ARCOS data to calculate the MME of opioids distributed by CVS by filtering the data to the shipments into Cuyahoga and Summit Counties based on the values in the "Buyer County" field and excluded non-CVS distributors using the "Reporter Name" field. Next, I used the "Calc Base Weight in GM" field to calculate the MME of each shipment by multiplying the weight of each transaction by 1,000 to convert to milligrams and multiplying by the corresponding MME conversion factor. Then, I calculated the MME of all opioids shipped into Cuyahoga and Summit Counties using the ARCOS data.<sup>45</sup> To calculate the total MME of prescription opioids shipped into Cuyahoga and Summit Counties, I filtered the ARCOS data to transactions shipped into Cuyahoga and Summit Counties using the values in the "Buyer County" field. Using the filtered data, I converted the weight of the active ingredient in the "Calc Base Weight in GM" field to milligrams by multiplying by a factor of 1,000 and then converted MME by multiplying the weight by each drug's corresponding MME conversion factor per the CDC.<sup>46</sup>
32. I compared the CVS opioid MME distribution, which as noted above was comprised only of HCPs, to the total opioid MME distributed into Cuyahoga and Summit Counties for 1/1/2006 through 12/31/2014, as well as annually using the "Transaction Date" field. I determined that CVS's opioid distribution is 2.3% of the entire opioid MME distributed into Cuyahoga County and 2.0% of the entire opioid MME distributed into Summit County.

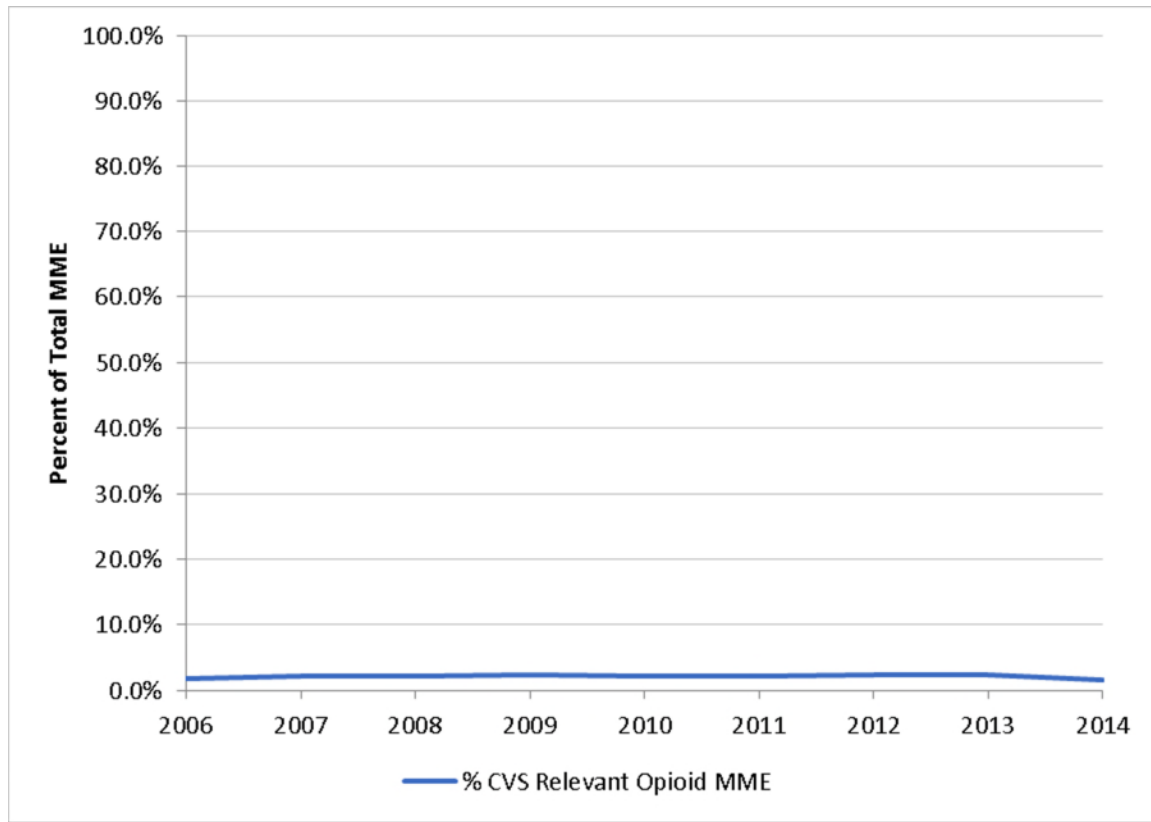
<sup>42</sup> Discovery Ruling No. 2. June 30, 2018, p. 3.

<sup>43</sup> Centers for Disease Control and Prevention, <https://www.cdc.gov/drugoverdose/resources/data.html>.

<sup>44</sup> "Calculating Total Daily Dose of Opioids For Safer Dosage," [https://www.cdc.gov/drugoverdose/pdf/calculating\\_total\\_daily\\_dose-a.pdf](https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf).

<sup>45</sup> This analysis uses the filtered ARCOS data, as described in Section III of this report.

<sup>46</sup> National Center for Injury Prevention and Control. CDC compilation of benzodiazepines, muscle relaxants, stimulants, zolpidem, and opioid analgesics with oral morphine milligram equivalent conversion factors, 2018 version. Atlanta, GA: Centers for Disease Control and Prevention; 2018. Available at <https://www.cdc.gov/drugoverdose/resources/data.html>.

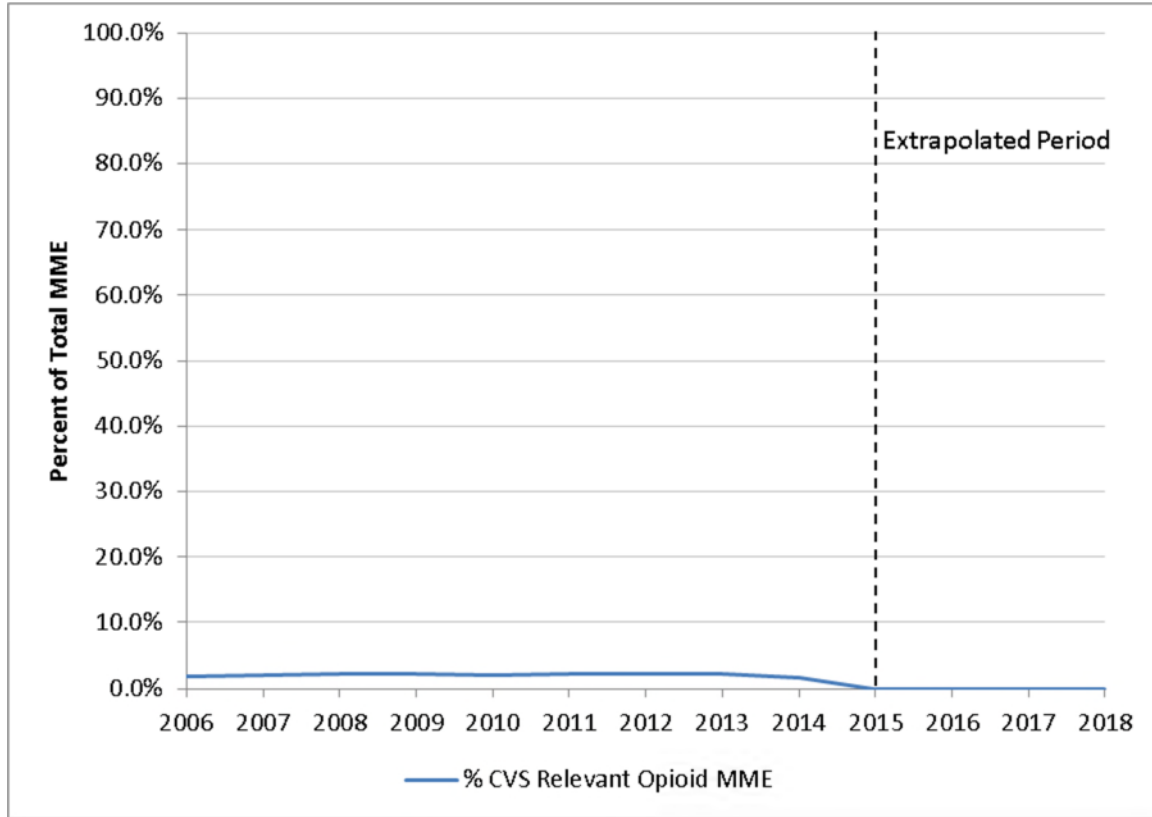
**Chart 2: Percentage of Total MME to Cuyahoga and Summit Counties (2006 – 2014)**

33. I also compared CVS's distribution of all opioids to the market for the period through 12/31/2018. To do so, I extrapolated the ARCOS data from 1/1/2015 through 12/31/2018 for all opioid shipments.<sup>47</sup> I calculated the average growth rate of total opioid shipments from the last three years of available ARCOS data separately for Cuyahoga and Summit Counties. From this data, I calculated the average growth rate between 2012 and 2014 to be -5.1% per year for Cuyahoga County, and -7.6% per year for Summit County. To estimate the total annual opioid MME for years from 2015 through 2018, I multiplied the prior year's total opioid MME by the average growth rate separately for Cuyahoga and Summit Counties. I then summed the total opioid MME for all distributors in ARCOS for 2006 to 2018 from Cuyahoga and Summit Counties to calculate the total opioid MME for all distributors.
34. Between 2006 and 2018, CVS distributed 1.6% of the total opioid MME into Cuyahoga and Summit Counties. Specifically, for Cuyahoga County, CVS distributed 1.6% of the total opioid MME, and for Summit County, CVS distributed 1.5% of the total opioid MME.

<sup>47</sup> HCP shipments by CVS Distribution ended in September 2014, before the end of the ARCOS data and, therefore, I have not extrapolated CVS HCP shipments.



**Chart 3: Percentage of Total MME to Cuyahoga and Summit Counties (2006 – 2018)  
(Extrapolated)**



#### **XI. THE ANNUAL DEA QUOTA WAS INCREASING AT A GREATER RATE THAN CVS SHIPMENTS OF HYDROCODONE COMBINATION PRODUCTS**

35. The Controlled Substances Act requires that the Attorney General set “quotas for each basic class of controlled substance in schedules I and II and for ephedrine, pseudoephedrine, and phenylpropanolamine” each year.<sup>48</sup> DEA issues and administers regulations setting three quotas: the aggregate production quota for total annual production, individual manufacturing quotas, and procurement quotas.<sup>49</sup> The aggregate production quota is the total amount of each basic class of Schedule I and II controlled substances that can be manufactured nationally in a year.<sup>50</sup> When establishing this quota, DEA considers the quantity of the class of controlled substance “necessary to be manufactured during the following calendar year to provide for the estimated medical, scientific,

<sup>48</sup> 21 U.S.C. § 826(a).

<sup>49</sup> 21 CFR §§ 1303.11, 1303.12, 1303.21.

<sup>50</sup> 21 C.F.R. § 1303.11(a).



research and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks.”<sup>51</sup>

36. Specific to the aggregate production quota for Hydrocodone, Stacey Harper-Avilla, the Section Chief for DEA’s UN Reporting & Quota Section testified that “DEA set[s] an aggregate production quota for the total amount of Hydrocodone that can be manufactured in a given year”<sup>52</sup> and with respect to hydrocodone used in HCPs, she testified that “the amount of Hydrocodone used counts against the quota amount[.]”<sup>53</sup>
37. To evaluate how the increase or decrease in CVS shipments of HCPs compared to the increase or decrease in the market, I compared CVS shipments into Summit and Cuyahoga counties in the ARCOS data<sup>54</sup> to the national DEA annual quotas.<sup>55</sup> Specifically, I compared the weight of HCP shipments in the ARCOS data to the weight of the hydrocodone manufacturing quota from the DEA.<sup>56</sup>
38. The ARCOS data includes the “Calc Base Weight in GM,” field which contains the base weight in grams of the primary active ingredient of the drug shipped. I filtered the ARCOS data to HCP shipments by filtering to records with the value of “9193” in the “Drug Code” field and filtered to transactions reported by CVS to arrive at the HCP shipments distributed by CVS. I calculated the total “Calc Base Weight in GM” of HCPs shipped by CVS by year using the year of the transaction date. I also converted the DEA Quotas into grams by multiplying the quotas by 1,000 to be on the same terms as the total calculated base weight from the ARCOS data.

<sup>51</sup> 21 C.F.R. § 1303.11(a).

<sup>52</sup> Deposition of Stacey Harper-Avilla at p. 107, line 16-19.

<sup>53</sup> Deposition of Stacey Harper-Avilla at p. 107, line 21-24.

<sup>54</sup> This analysis uses the filtered ARCOS data, as described in Section III of this report.

<sup>55</sup> [https://www.deadiversion.usdoj.gov/quotas/year\\_end/index.html](https://www.deadiversion.usdoj.gov/quotas/year_end/index.html).

<sup>56</sup> Aggregate Production Quota History for Selected Substances, Updated January 22, 2019, [https://www.deadiversion.usdoj.gov/quotas/quota\\_history.pdf](https://www.deadiversion.usdoj.gov/quotas/quota_history.pdf); Final Revised Aggregate Production Quotas for 2006, 71 Fed. Reg., 61803, 61805 (Oct. 19, 2006); Final Revised Aggregate Production Quotas for 2007, 72 Fed. Reg., 48686, 48688 (Aug. 24, 2007); Final Revised Aggregate Production Quotas for 2008, 73 Fed. Reg., 66939, 66941 (Nov. 12, 2008); Final Revised Aggregate Production Quotas for 2009, 74 Fed. Reg., 54077, 54079 (Oct. 21, 2009)





39. While the aggregate weight of hydrocodone distributed by CVS increased over the period from 2006 to 2013, that increase is at a lower rate than the increase in the DEA Quota for hydrocodone. Put differently, based on DEA's assessment of the amount of hydrocodone needed for legitimate purposes, DEA increased the aggregate hydrocodone quota at a rate greater than the increases in CVS shipments of HCPs to Cuyahoga and Summit counties. Table 3 below shows that the nominal weight of CVS HCP shipments increased from approximately 20 thousand grams in 2006 to approximately 29 thousand grams in 2013, the last full year during which CVS distributed HCPs. During the same period, the DEA quota more than doubled.

**Table 3: Percentage Change in CVS HCP Shipments (in grams)  
and DEA Hydrocodone Quota (in grams)**

Year	CVS HCP Weight – ARCOS Data (in g)	DEA Hydrocodone Quota (in g)	% Change in CVS HCP Weight (ARCOS)	% Change in Hydrocodone Quota (DEA)
2006	19,793	42,000,000		
2013	28,865	99,625,000	45.8%	137.2%

## **XII. CONTROLLED SUBSTANCES REPRESENT LESS THAN 5.5% OF SHIPMENTS, LESS THAN 3.5% OF PACKAGES, AND LESS THAN 10.5% OF DOSAGE UNITS SHIPPED TO CVS PHARMACIES IN CUYAHOGA AND SUMMIT COUNTIES BY CVS DISTRIBUTION CENTERS**

40. To evaluate the profile of shipments from CVS, I analyzed the composition of shipments of controlled versus non-controlled items in the CVS distribution data. As described above, the data contains information about CVS shipments of items dispensed from the pharmacy in a CVS store. The data does not include non-controlled items that are sold from the other areas of a CVS store such as pain relievers (e.g., Advil or Tylenol) and cold remedies, including Pseudoephedrine products like Sudafed, that do not require a prescription.<sup>57</sup> If those items were included, the percentage of controlled substances calculated in the analysis below would be lower and the percentage of non-controlled substances would be higher. Transactions in the CVS distribution data identify the item shipped by National Drug Code (NDC), which is redacted for all transactions other than for the prescription opioids at issue in this case.<sup>58</sup> Additionally, each transaction lists the number of the packages shipped

<sup>57</sup> John Andrade, Senior Manager, Application Development, IS – Retail Systems - Logistics

<sup>58</sup> Letter from Paul Hynes, Jr., Zuckerman Spaeder LLP, dated May 8, 2019.



(Regular Quantity) and the "Drug Control Indicator" marks transactions with controlled substances with a "1."<sup>59</sup>

41. First, I compared the number of shipments (transactions) containing controlled substances to those that did not contain controlled substances. To perform this comparison, I identified shipments of controlled substances as those transactions with a value of "1" in the "Drug Control Indicator" field and transactions without a "1" as shipments of non-controlled substances. Then, I quantified the number of transactions in each group across the entire period, on an annual basis, and by store.
42. I found that from January 2006 through September 2014, CVS shipments of controlled substances were 5.4% of total shipments into Cuyahoga and Summit Counties. Furthermore, on an annual basis between January 2006 and September 2014, the percentage of controlled substances distributed ranges between 5.2% and 5.8% of total shipments made. Table 4 summarizes the results of this analysis.

**Table 4: Proportion of Controlled and Non-Controlled Substances Shipped By CVS Distribution Centers to CVS Pharmacies in Cuyahoga and Summit Counties by Shipment**

<b>Year</b>	<b>% of Shipments - Controlled</b>	<b>% of Shipments - Non-Controlled</b>
2006	5.4%	94.6%
2007	5.5%	94.5%
2008	5.8%	94.2%
2009	5.8%	94.2%
2010	5.8%	94.2%
2011	5.8%	94.2%
2012	5.8%	94.2%
2013	5.8%	94.2%
2014	5.2%	94.3%
<b>Total:</b>	<b>5.7%</b>	<b>94.3%</b>

43. Additionally, when looking at this comparison by store, shipments of controlled substances represent less than 8.0% of total shipments to each store by CVS distribution centers. Exhibit 8C summarizes the results of this analysis for each store in the CVS distribution data.
44. After evaluating the composition of shipments, I evaluated the composition of packages shipped by CVS during this period using the "Regular Quantity" field. Again, I identified shipments of controlled

<sup>59</sup> See footnote 9.



substances as having a "1" in the "Drug Control Indicator" field and calculated the total packages shipped with controlled versus non-controlled packages distributed by CVS to its pharmacies across the period, by year, and by store. I determined that over the period, 3.3% of packages shipped by CVS of controlled substances. By year, the number of packages shipped of controlled substances ranged between 2.8% and 4.1%. Table 5 summarizes the results of this analysis.

**Table 5: Proportion of Controlled and Non-Controlled Substances Shipped by CVS Distribution Centers to CVS Pharmacies in Cuyahoga and Summit Counties by Package**

Year	% of Packages - Controlled	% of Packages - Non-Controlled
2006	2.8%	97.2%
2007	3.0%	97.0%
2008	3.2%	96.8%
2009	3.1%	96.9%
2010	3.1%	96.9%
2011	4.1%	95.9%
2012	3.9%	96.1%
2013	3.0%	97.0%
2014	3.0%	97.0%
<b>Total:</b>	<b>3.3%</b>	<b>96.7%</b>

45. Exhibit 9C summarizes the results of this analysis for each store in the CVS distribution data.

46. In addition, I evaluated the dosage units of controlled items shipped versus shipments of non-controlled items by CVS distribution centers to CVS pharmacies across the period, by year, and by store. I determined that 10.2% of dosage units shipped by CVS distributors represented controlled substances. On an annual basis, the percentage of dosage units of controlled substances shipped ranged between 9.0% and 11.0%. Table 6 summarizes the results of this analysis.

**Table 6: Proportion of Controlled and Non-Controlled Substances Shipped by CVS Distribution Centers to CVS Pharmacies in Cuyahoga and Summit Counties by Dosage Unit**

Year	% Dosage Units - Controlled	% Dosage Units - Non-Controlled
2006	10.0%	90.0%
2007	10.2%	89.8%



2008	11.0%	89.0%
2009	10.6%	89.4%
2010	10.0%	90.0%
2011	10.6%	89.4%
2012	10.7%	89.3%
2013	9.8%	90.2%
2014	9.0%	91.0%
<b>Total:</b>	<b>10.2%</b>	<b>89.8%</b>

47. Exhibit 10C summarizes the results of this analysis for each store in the CVS distribution data.

**XIII. HYDROCODONE COMBINATION PRODUCTS REPRESENT LESS THAN 1.0% OF SHIPMENTS, LESS THAN 0.6% OF PACKAGES, AND LESS THAN 2.5% OF DOSAGE UNITS SHIPPED TO CVS PHARMACIES BY CVS DISTRIBUTION CENTERS**

48. Next, I evaluated shipments of HCPs against shipments of all other items. I identified shipments of HCPs as those with unredacted NDC numbers.<sup>60</sup> I calculated the total number of shipments of HCPs and those related to shipments of other items and calculated the proportion across the entire period, annually, and by store.

49. I found that from January 2006 through September 2014, shipments of HCPs comprised 1.2% of the total number of shipments in the CVS distribution data. On an annual basis, the shipments range between 1.1% and 1.5% of the total number of shipments. Table 7 summarizes the results of this analysis.

**Table 7: Proportion of HCP and Non-HCP Shipments by CVS Distribution Centers to CVS Pharmacies in Cuyahoga and Summit Counties by Shipment**

Year	% of Shipments – HCP	% of Shipments - Non-HCP
2006	1.2%	98.8%
2007	1.2%	98.8%
2008	1.2%	98.8%
2009	1.2%	98.8%
2010	1.2%	98.8%
2011	1.3%	98.7%
2012	1.3%	98.7%
2013	1.5%	98.5%

<sup>60</sup> These shipments correlate with the shipments of HCPs by CVS Reporters in the ARCOS data.



2014	1.1%	98.9%
<b>Total:</b>	<b>1.2%</b>	<b>98.8%</b>

50. Additionally, when looking at this comparison by store, shipments to each store of HCPs are 2.0% or less of the total shipments to each store. Exhibit 11C summarizes the results of this analysis for each store in the CVS distribution data.

51. Next, I quantified the total number of packages of HCPs shipped versus shipments of other items by CVS distribution centers to CVS pharmacies across the period, by year, and by store. I determined that 0.7% of packages shipped by CVS distribution centers of HCPs. On an annual basis, the percentage of packages of HCPs shipped ranged between 0.6% and 1.0%. Table 8 summarizes the results of this analysis.

**Table 8: Proportion of HCP and Non-HCP Shipments  
by CVS Distribution Centers to CVS Pharmacies  
in Cuyahoga and Summit Counties by Package**

<b>Year</b>	<b>% of Packages - HCP</b>	<b>% of Packages - Non-HCP</b>
2006	0.6%	99.4%
2007	0.7%	99.3%
2008	0.7%	99.3%
2009	0.7%	99.3%
2010	0.6%	99.4%
2011	0.7%	99.3%
2012	0.6%	99.4%
2013	0.8%	99.2%
2014	1.0%	99.0%
<b>Total:</b>	<b>0.7%</b>	<b>99.3%</b>

52. When looking at this comparison by store, shipped packages to each store of HCPs are less than 1.5% of the total shipped packages to each store. Exhibit 12C summarizes the results of this analysis for each store in the CVS distribution data.

53. Next, I assessed the total number of dosage units of HCPs shipped versus shipments of other items by CVS distribution centers to CVS pharmacies across the period, by year, and by store. I determined that 3.4% of dosage units shipped by CVS distributors were HCPs. On an annual basis, the percentage of dosage units shipped of HCPs ranged between 2.6% and 3.8%. Table 9 summarizes the results of this analysis.



**Table 9: Proportion of HCP and Non-HCP Shipments  
by CVS Distribution Centers to CVS Pharmacies  
in Cuyahoga and Summit Counties by Dosage Unit**

<b>Year</b>	<b>% Dosage Units - HCP</b>	<b>% Dosage Units - Non-HCP</b>
2006	3.5%	96.5%
2007	3.7%	96.3%
2008	3.8%	96.2%
2009	3.7%	96.3%
2010	3.5%	96.5%
2011	3.7%	96.3%
2012	3.4%	96.6%
2013	3.0%	97.0%
2014	2.6%	97.4%
<b>Total:</b>	<b>3.4%</b>	<b>96.6%</b>

54. Exhibit 13C summarizes the results of this analysis for each store in the CVS distribution data.

**XIV. CONTROLLED SUBSTANCES REPRESENT LESS THAN 8.5% OF SHIPMENTS, LESS THAN 6.2% OF PACKAGES, AND LESS THAN 13.5% OF DOSAGE UNITS SHIPPED TO CVS PHARMACIES IN CUYAHOGA AND SUMMIT COUNTIES BY CVS DISTRIBUTION CENTERS AND CARDINAL HEALTH COMBINED**

55. I also evaluated the ratio of controlled to non-controlled shipments for all shipments to CVS pharmacies in Cuyahoga and Summit counties. CVS is not the only distributor from whom CVS pharmacies receive shipments. Cardinal Health also distributes to CVS pharmacies. CVS's corporate representative testified that "If a CVS pharmacy, prior to 2014 wanted to purchase a hydrocodone drug from an outside vendor, such as McKesson or Cardinal, that CVS drugstore [would] place order directly with the outside vendor," and that "order would be delivered directly from the outside distributor, McKesson or Cardinal, directly to the pharmacy."<sup>61</sup> Cardinal Health is the primary outside distributor to CVS pharmacies located in Ohio.<sup>62</sup>

56. I first combined the CVS distribution data with the Cardinal Health distribution data for the period between January 2006 and September 2014. After combining the CVS distribution data and the

<sup>61</sup> Deposition of Mark Vernazza, November 20<sup>th</sup>, 2018, p. 46, line 11 through p. 47, line 14.

<sup>62</sup> Brian Whalen, Vice President, Pharmacy Merchandising; CVS #2932-CareCenter Pharmacy, L.L.C. was not a typical CVS pharmacy, but rather an on-site pharmacy for clients of CVS's PBM business. McKesson Corporation was the distributor for CareCenter pharmacies, and I have, therefore, excluded store #2932 from this analysis.



Cardinal Health distribution data for this period, I assigned a Drug Control Indicator value to the Cardinal Health distribution data based on the NDC information from both the ARCOS Transaction data and the NDC dictionary.<sup>63</sup> If an NDC Number was found in the NDC Dictionary or the ARCOS Transaction data, that record was flagged as a controlled substance within the Cardinal Health distribution data. I used the "Drug Control Indicator" field available in the CVS distribution data to identify controlled substances shipped by CVS. Then, I evaluated the ratio of controlled shipments to non-controlled shipments to CVS pharmacies, from CVS and Cardinal Health.

57. I found that from January 2006 through September 2014, shipments of controlled substances to CVS pharmacies in Cuyahoga and Summit Counties were 8.5% of total shipments. Furthermore, on an annual basis between 2006 and 2014, the percentage of controlled substances shipped ranged between 7.4% and 9.0% of total shipments. Table 10 summarizes the results of this analysis.

**Table 10: Proportion of Controlled and Non-Controlled Substances Shipped to CVS Pharmacies in Cuyahoga and Summit Counties by Shipment**

Year	% of Shipments - Controlled	% of Shipments – Non-Controlled
2006	7.4%	92.6%
2007	7.9%	92.1%
2008	8.2%	91.8%
2009	8.6%	91.4%
2010	8.9%	91.1%
2011	8.9%	91.1%
2012	8.9%	91.1%
2013	9.0%	91.0%
2014	8.6%	91.4%
<b>Total:</b>	<b>8.5%</b>	<b>91.5%</b>

58. Exhibit 14C summarizes the results of this analysis for each store in the CVS distribution data.

59. After evaluating the composition of shipments, I evaluated the composition of total packages shipped to CVS pharmacies during this period using the "Regular Quantity" field from the CVS distribution data and the "Qty\_Ship" field from the Cardinal Health distribution data. I used the same process described above to identify controlled substances in the CVS distribution data and Cardinal Health distribution data.

<sup>63</sup> "National Drug Code Dictionary", <https://www.deadiversion.usdoj.gov/arcos/ndc/ndcfile.txt>.



60. I determined that over this period, 6.2% of all packages shipped to CVS pharmacies were for controlled substances. By year, the number of packages of controlled substances shipped ranged between 5.1% and 7.3%. Table 11 summarizes the results of this analysis.

**Table 11: Proportion of Controlled and Non-Controlled Substances Shipped to CVS Pharmacies in Cuyahoga and Summit Counties by Package**

Year	% of Packages – Controlled	% of Packages – Non-Controlled
2006	5.1%	94.9%
2007	5.7%	94.3%
2008	6.1%	93.9%
2009	6.1%	93.9%
2010	6.3%	93.7%
2011	7.3%	92.7%
2012	6.8%	93.2%
2013	6.2%	93.8%
2014	6.0%	94.0%
<b>Total:</b>	<b>6.2%</b>	<b>93.8%</b>

61. Exhibit 15C summarizes the results of this analysis for each store in the CVS distribution data.

62. After evaluating the composition of packages, I evaluated the composition of total dosage units shipped to CVS pharmacies during this period using the "Regular Quantity" and "Size" fields from the CVS distribution data and the "Qty\_Ship" and "Size" fields from the Cardinal Health distribution data. I multiplied the two fields together from the respective sources to derive the total dosage units in each shipment. I used the same process described above to identify controlled substances in the CVS distribution data and Cardinal Health distribution data.

63. I determined that, over the period, 13.4% of all dosage units shipped to CVS pharmacies were controlled substances. By year, the number of dosage units of controlled substances ranged between 12.1% and 14.2%. Table 12 summarizes the results of this analysis.





**Table 12: Proportion of Controlled and Non-Controlled Substances Shipped to CVS Pharmacies in Cuyahoga and Summit Counties by Dosage Unit**

Year	% of Dosage Units – Controlled	% of Dosage Units – Non-Controlled
2006	12.1%	87.9%
2007	13.0%	87.0%
2008	13.9%	86.1%
2009	13.7%	86.3%
2010	13.7%	86.3%
2011	14.2%	85.8%
2012	14.0%	86.0%
2013	13.1%	86.9%
2014	12.1%	87.9%
<b>Total:</b>	<b>13.4%</b>	<b>86.6%</b>

64. Exhibit 16C summarizes the results of this analysis for each store.

**XV. HYDROCODONE COMBINATION PRODUCTS REPRESENT LESS THAN 1.1% OF SHIPMENTS, LESS THAN 0.7% OF PACKAGES, AND LESS THAN 3.1% OF DOSAGE UNITS SHIPPED TO CVS PHARMACIES IN CUYAHOGA AND SUMMIT COUNTIES BY CVS DISTRIBUTION CENTERS AND CARDINAL HEALTH COMBINED**

65. Next, I evaluated shipments of HCPs against shipments of all other pharmacy items. I identified shipments of HCPs as those with unredacted NDC numbers in the CVS distribution data,<sup>64</sup> and the "DEA\_Base\_Desc" field in the Cardinal Health distribution data.<sup>65</sup> I calculated the total number of shipments of HCPs and those related to shipments of other drugs and calculated the proportion across the entire period, annually, and by store.

66. I found that from January 2006 through September 2014, shipments of HCPs comprised 1.1% of the total number of shipments to CVS pharmacies in Cuyahoga and Summit Counties. On an annual basis, the shipments ranged between 0.9% and 1.2% of the total number of shipments to CVS pharmacies. Table 13 summarizes the results of this analysis.

<sup>64</sup> These shipments correlate with the shipments of HCPs by CVS Reporters in the ARCOS data.

<sup>65</sup> See footnote 62.



**Table 13: Proportion of HCP and Non-HCP Shipments to CVS Pharmacies in Cuyahoga and Summit Counties by Shipment**

Year	% of Shipments - HCP	% of Shipments - Non-HCP
2006	1.1%	98.9%
2007	1.1%	98.9%
2008	1.1%	98.9%
2009	1.1%	98.9%
2010	1.1%	98.9%
2011	1.1%	98.9%
2012	1.1%	98.9%
2013	1.2%	98.8%
2014	0.9%	99.1%
<b>Total:</b>	<b>1.1%</b>	<b>98.9%</b>

67. Additionally, when looking at this comparison by store, shipments to each store of HCPs are 1.7% or less of the total shipments to each store. Exhibit 17C summarizes the results of this analysis for each store in the CVS and Cardinal Health distribution data.

68. Next, I quantified the total number of packages of HCPs shipped versus packages of other drugs to CVS pharmacies in Summit and Cuyahoga Counties from both CVS and Cardinal Health across the period, by year, and by store. I determined that 0.7% of packages shipped to CVS pharmacies were HCPs. On an annual basis, the percentage of packages shipped of HCPs ranged between 0.6% and 0.9%. Table 14 summarizes the results of this analysis.

**Table 14: Proportion of HCP and Non-HCP Shipments to CVS Pharmacies in Cuyahoga and Summit Counties by Package**

Year	% of Packages - HCP	% of Packages - Non-HCP
2006	0.6%	99.4%
2007	0.7%	99.3%
2008	0.7%	99.3%
2009	0.6%	99.4%
2010	0.6%	99.4%
2011	0.6%	99.4%
2012	0.6%	99.4%
2013	0.7%	99.3%
2014	0.9%	99.1%
<b>Total:</b>	<b>0.7%</b>	<b>99.3%</b>



69. When looking at this comparison by store, shipped packages to each store of HCPs are less than 1.5% of the total shipped packages to each store. Exhibit 18C summarizes the results of this analysis for each store in the CVS and Cardinal Health distribution data.

70. Next, I quantified the total number of dosage units of HCPs shipped versus dosage units of other drugs shipped to CVS pharmacies in Summit and Cuyahoga Counties from both CVS distribution centers and Cardinal Health during this period, by year, and by store. I determined that 3.0% of dosage units shipped to CVS pharmacies were HCPs. On an annual basis, the percentage of dosage units of HCPs shipped ranged between 2.3% and 3.5%. Table 15 summarizes the results of this analysis.

**Table 15: Proportion of HCP and Non-HCP Shipments to CVS Pharmacies in Cuyahoga and Summit Counties by Dosage Unit**

Year	% of Dosage Units - HCP	% of Dosage Units - Non-HCP
2006	3.2%	96.8%
2007	3.4%	96.6%
2008	3.5%	96.5%
2009	3.3%	96.7%
2010	3.1%	96.9%
2011	3.2%	96.8%
2012	3.0%	97.0%
2013	2.6%	97.4%
2014	2.3%	97.7%
<b>Total:</b>	<b>3.0%</b>	<b>97.0%</b>

71. When looking at this comparison by store, shipped dosage units to each store of HCPs are 5.4% or less of the total shipped dosage units to each store. Exhibit 19C summarizes the results of this analysis for each store in the CVS and Cardinal Health distribution data.

#### **XVI. CVS PHARMACIES ORDERED A SMALL PERCENTAGE OF HYDROCODONE COMBINATION PRODUCTS FROM ITS OUTSIDE VENDOR CARDINAL HEALTH**

72. I next evaluated the proportion of HCP shipments that CVS pharmacies received from CVS and Cardinal Health.<sup>66</sup> I first combined the CVS distribution data with the Cardinal Health distribution data

<sup>66</sup> See footnote 62.



using the process described above. Then, I quantified the percentage of HCP packages received by CVS pharmacies that were shipped from CVS versus those shipped from Cardinal Health.

73. Between January 2006 and September 2014, CVS distribution centers shipped 92.4% of all HCP packages to CVS pharmacies in Cuyahoga and Summit counties, with 7.6% of HCP packages received from Cardinal Health.

**Table 16: Proportion of HCP Packages Shipped to CVS Pharmacies in Cuyahoga and Summit Counties by CVS and Cardinal Health**

Year	% of HCP Packages from Cardinal Health	% HCP Packages from CVS
2006	6.8%	93.2%
2007	7.0%	93.0%
2008	10.3%	89.7%
2009	9.5%	90.5%
2010	6.3%	93.7%
2011	6.0%	94.0%
2012	9.0%	91.0%
2013	8.7%	91.3%
2014	4.8%	95.2%
<b>Total:</b>	<b>7.6%</b>	<b>92.4%</b>

74. During the period 2006 through 2014, Cardinal Health never distributed more than 10.3% of all HCP packages to CVS pharmacies in Cuyahoga and Summit counties.

75. I also analyzed the distribution of dosage units for HCPs shipped to CVS pharmacies, both by CVS and Cardinal Health between January 2006 and September 2014.<sup>67</sup>

**Table 17: Proportion of HCP Dosage Units Shipped to CVS Pharmacies in Cuyahoga and Summit Counties by CVS and Cardinal Health**

Year	% of HCP Dosage Units from Cardinal Health	% HCP Dosage Units from CVS
2006	5.8%	94.2%
2007	5.6%	94.4%
2008	7.5%	92.5%
2009	6.4%	93.6%

<sup>67</sup> See footnote 62.



2010	4.0%	96.0%
2011	3.5%	96.5%
2012	5.5%	94.5%
2013	7.3%	92.7%
2014	6.7%	93.6%
<b>Total:</b>	<b>5.7%</b>	<b>94.3%</b>

76. CVS distributed 94.3% of all HCP dosage units to CVS pharmacies in Cuyahoga and Summit counties through September 2014.

77. I also evaluated and quantified the percentage of non-controlled packages received by CVS pharmacies in Cuyahoga and Summit counties that were shipped by CVS versus shipped from Cardinal Health.<sup>68</sup>

78. During this period, CVS shipped 90.5% of non-controlled packages to CVS pharmacies, with 9.5% of non-controlled packages received from Cardinal Health for the period 2006 through September 2014.

**Table 18: Proportion of Non-Controlled Packages Shipped to CVS Pharmacies in Cuyahoga and Summit Counties by CVS and Cardinal Health**

<b>Year</b>	<b>% Non-Controlled Packages from Cardinal Health</b>	<b>% Non-Controlled Packages from CVS</b>
2006	8.4%	91.6%
2007	8.2%	91.8%
2008	8.1%	91.9%
2009	8.3%	91.7%
2010	8.3%	91.7%
2011	9.4%	90.6%
2012	10.3%	89.7%
2013	11.4%	88.6%
2014	12.1%	87.9%
<b>Total:</b>	<b>9.5%</b>	<b>90.5%</b>

79. I also quantified the percentage of non-controlled dosage units received by CVS pharmacies that were shipped by CVS versus shipped from Cardinal Health for the relevant period, January 2006 through September 2014.<sup>69</sup>

<sup>68</sup> See footnote 62.

<sup>69</sup> See footnote 62.



80. I calculated that CVS shipped 86.1% of all non-controlled dosage units to CVS pharmacies, with 13.9% of non-controlled dosage units received from Cardinal Health.

**Table 19: Proportion of Non-Controlled Dosage Units Shipped to CVS Pharmacies in Cuyahoga and Summit Counties by CVS and Cardinal Health**

Year	% Non-Controlled Dosage Units from Cardinal Health	% Non-Controlled Dosage Units from CVS
2006	13.4%	86.6%
2007	12.8%	87.2%
2008	13.6%	86.4%
2009	13.3%	86.7%
2010	11.6%	88.4%
2011	12.2%	87.8%
2012	14.4%	85.6%
2013	16.2%	83.8%
2014	16.7%	83.3%
<b>Total:</b>	<b>13.9%</b>	<b>86.1%</b>

## **XVII. CONCLUSION**

81. Based upon my review of the data and documents produced in this case, I found that CVS did not distribute HCPs into Cuyahoga and Summit counties after October 6, 2014 when DEA rescheduled hydrocodone combination products to Schedule II. I also found that CVS did not distribute any Schedule II drugs into Cuyahoga and Summit counties during the relevant period. During the period in which CVS was shipping HCPs, CVS shipped 2.1% of the relevant prescription opioids being distributed in Cuyahoga and Summit counties.
82. From the CVS distribution data, I calculated that controlled substances shipped by CVS represent less than 10.5% of dosage units it shipped to CVS pharmacies into Cuyahoga and Summit counties between 2006 and 2014. Furthermore, HCP shipments were less than 3.5% of total dosage units shipped by CVS during this period into Cuyahoga and Summit counties.
83. I calculated that controlled substances from Cardinal Health and CVS together represent less than 13.5% of total dosage units shipped to CVS pharmacies into Cuyahoga and Summit counties between 2006 and 2014. HCP shipments from Cardinal Health and CVS were less than 3.0% of total dosage units shipped to CVS pharmacies during this period.
84. To the extent any additional information is produced by either party, I reserve the right to incorporate such additional information into my report. This report was prepared solely for the



above-captioned matter and should not be used for any other purpose without prior written authorization.

BY:

A handwritten signature in blue ink, appearing to read "Sonya Kwon".

SONYA KWON

Dated: 5/10/2019